UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)(KMW)**

PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE TESTIMONY OF JOHN M. FLACK, M.D.

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I. INTRODUCTION

John M. Flack is a Medical Doctor and MPH Epidemiologist, retained by Teva and/or all defendants,[1] who submitted an Expert Report purportedly aimed at disputing general causation in this matter. Dr. Flack, by his own admission, has no experience whatsoever with any of the issues pertaining to general causation in this case, including: (1) NDMA or NDEA (or any nitrosamines for that matter); (2) toxicology generally; (3) oncology or cancer research. Rather, Dr. Flack rests his opinion entirely on his background as a purported epidemiologist, and a so-called "literature review" he referenced in his Report.

By Dr. Flack's own admission, his Report in this case would be "blasted" in academia for its grave methodological shortcomings. Specifically, and among other glaring and fatal deficiencies in his "literature review," Dr. Flack: (1) failed to analyze or consider entire categories of scientific evidence bearing directly on the question he attempts to answer; and (2) for the cherry-picked studies he did discuss, Dr. Flack was unable to address the limitations of the studies when pressed in his deposition, including shortcomings identified by the study authors themselves. These and other failures discussed below render Dr. Flack's opinions unreliable to the point of exclusion pursuant to Fed. R. Evid. 702.

II. APPLICABLE LAW

A. Fed. R. Civ. P. 26 and the Contents of the Expert Report

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony and specifically the contents of an expert report. As relevant to this Motion, the Rule states the following: "The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in

[1] Dr. Flack himself seemed uncertain whether his Report applied only to Teva or to all of the defendants.

forming them ….” Fed. R. Civ. P. 26(a)(2)(B)(i) & (ii). A failure to submit an expert report that complies with Rule 26 is an independent basis for the exclusion of the expert’s testimony. *See, e.g., Meyers v. Nat’l R.R. Pass. Corp. (Amtrak)*, 619 F.3d 729, 734 (7th Cir. 2010) (“The consequence of non-compliance with Rule 26(a)(2)(B) is exclusion of an expert’s testimony[.]” (internal quotations and citations omitted)).

B. *Daubert* Standard

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.,* 186 F.3d 412, 417-18 (3d Cir. 1999). An “expert’s opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation.” *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, “the expert must have ‘good grounds’ for his or her belief.” *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, “*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *Id.* at 745. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Paoli*, 35 F.3d at 742 (discussing reliability factors under *Daubert* and Third Circuit case law).

Furthermore, “*Daubert*'s gatekeeping requirement .... make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); *see also Magistrini v. One Hour Martinizing Dry*

Cleaning, 180 F.Supp.2d 584, 594 (D.N.J.2002*), aff'd,* 68 Fed. Appx. 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

> (i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner,* 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)); (iii) whether the expert has adequately accounted for alternative explanations (*see Claar v. Burlington, N.R.R.,* 29 F.3d 499 (9th Cir. 1994)).

Magistrini, 180 F. Supp. 2d at 594–95.

C. *Daubert* and Epidemiology

"Epidemiology provides 'the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or disease.'" *In re Lipitor (Atorvastatin Calcium) Mkt'ing, Sales Practices and Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 914 (D.S.C. 2016) (citing cases). Epidemiologists use a two-part process for determining causation: (1) the presence of studies that establish an association between exposure to the chemical compound of concern and a disease; and (2) application of a weight of the evidence/Bradford Hill[2] analysis. *Id.* at 914-916; *see also In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 796-97 (3d Cir. 2017) ("Here, we accept that the Bradford hill and weight of the evidence analyses are generally reliable.").

As part of any reliable epidemiological study, it is imperative that the epidemiologist consider all of the various categories of key literature on the topic when conducting a weight of

[2] The Bradford Hill factors are: (1) strength of the association, (2) replication of the findings, (3) specificity of the association, (4) temporal relationship, (5) dose-response relationship (aka biological gradient), (6) biological plausibility, (7) consistency with other knowledge (aka coherence), (8) consideration of alternative explanations, and (9) cessation of exposure. *See In re Zoloft*, 858 F.3d at 795; *see also Reference Manual on Scientific Evidence (RMSE)*, at 600 (3d ed. 2011).

the evidence/Bradford Hill analysis. This epidemiological analysis cannot be applied reliably when the evidence itself is cherry-picked, excludes contrary evidence, or for whatever reason is materially incomplete. *In re Lipitor*, 174 F. Supp. 3d at 929-932; *see also Daniels-Feasel v. Forest Pharm., Inc.*, No. 17cv4188, 2021 WL 4037820, at *5 (S.D.N.Y. Sept. 3, 2021) (in context of addressing *Daubert* motion against an expert epidemiologist, stating that "[a]n expert must not cherry-pick from the scientific landscape … exclusion of proffered testimony is warranted where the expert fails to address evidence that is highly relevant to his or her conclusion" (attached hereto as **Ex. 4**)). At its root, a failure to collect and consider the evidence bearing on the question demonstrates an "[in]sufficiently rigorous analytical connection between that methodology and the expert's conclusions." *Nimely v. City of New York*, 414 F.3d 381, 396 (2d Cir. 2005).

III. ARGUMENT

A. Dr. Flack and His Expert Report

Dr. Flack is an internal medicine physician and purported epidemiologist. Dr. Flack's Expert Report (hereinafter "Flack Report" (**Ex. 1**)) contains several opinions relevant to this Motion:

> **(1)** Dr. Flack posits that hypertension patients appear to be at a greater baseline risk of cancer (Flack Report, Section III.O);
> **(2)** Dr. Flack attempts to answer the question of whether there is a "causal relationship" between NDMA/NDEA and cancer based on an epidemiological review of the evidence (Flack Report, Section VIII);
> **(3)** Dr. Flack asserts that "[he] did not witness any patients have an adverse effect as a result of the NDMA/NDEA impurities found in valsartan" based on his experience as a treating physician; and,
> **(4)** Dr. Flack opines that it is more likely that shared risk factors between hypertension and cancer contributed to patients' cancers than their exposure to NDMA/NDEA in Defendants' valsartan-containing drugs ("VCDs") (Flack Report, Section IX).

However, Dr. Flack's written opinions unraveled upon examination at his deposition. The testimony was filled with admissions that fatally undercut both Dr. Flack's qualifications, as well as the so-called methodology purporting to support the opinions set forth in the Report. Dr. Flack even disowned some of his Report's assertions.

B. Dr. Flack's Lack of Qualifications

Dr. Flack has never been qualified as an expert in any litigation relating to the toxicological nature of any chemical or the propensity of any chemical to cause cancer. (09/28/21 Deposition of John M. Flack (hereinafter "Flack Dep." (**Ex. 2**)), at 59:6-20.) Dr. Flack is an internist and does not hold any board certification or other specialization relating to oncology or toxicology. (Flack Dep. 64:7-15.) Dr. Flack has never once in his professional career had occasion to: (1) study NDMA or NDEA or nitrosamines (Flack Dep. 64:16-22, 78:6-10, 107:1-10 [redacted]); (2) study the toxicological nature and/or the propensity of *any* chemical structure to cause cancer (Flack Dep. 110:8-14 (Dr. Flack stating [redacted] or (3) study cancer at all (Flack Dep. 41:16-19 [redacted]). Not once, that is, until Dr. Flack submitted an expert report in this litigation. Courts are rightly skeptical of "litigation-driven expertise" wherein the proposed expert's "experience was developed for the litigation." *In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 240 (S.D.N.Y. 2018).

Even if Dr. Flack is found to be minimally qualified to proffer opinions as an epidemiologist, his non-epidemiology opinions cannot survive. This includes specifically Dr. Flack's naked assertion that he has "not witness[ed] any patients have an adverse effect as a result of the NDMA/NDEA impurities found in valsartan." (Flack Rep., at 30). As discussed below, aside from the methodological failure of doing absolutely nothing to rule out NDMA/NDEA as the cause of any of his patients' cancers, Dr. Flack retracted this opinion at his deposition. (Flack

Dep. 177:14-179:3 (clarifying that [redacted]).)

C. Dr. Flack's Epidemiological Opinion in Section VIII of His Report Addressing NDMA/NDEA and Cancer Causation Is Unreliable and Should Be Excluded

In Section VIII of his Report, Dr. Flack offers the opinion that "there is insufficient scientific evidence to establish that trace amounts of NDMA or NDEA in valsartan caused the types of cancers Plaintiffs allege in this litigation." (Flack Rep., at 31.) Dr. Flack states the following in his report:

> I have conducted a thorough review of the relevant literature on valsartan use and cancer incidence simply does not support a causal association between exposure to trace amounts of nitrosamines in valsartan and cancer development.

(Flack Rep., at 31.) Dr. Flack continues by describing "[his] assessment of the key literature" and then includes in his Report "a section on animal studies, a section on occupational studies, and … a section on the valsartan studies[.]" (Flack Rep., at 31-39; *see also* Flack Dep. 144:23-145:19.)

Dr. Flack's literature review, however, was anything but "thorough." Dr. Flack omitted entire categories of evidence from his analysis, most notably all of the human dietary studies addressed by Plaintiffs' epidemiologists (and even several of Defendants' other epidemiologists). As discussed below, he also ignored the mechanistic studies demonstrating that NDMA causes cancer in animals and humans in the same way – by altering DNA.

1. A Rigorous Literature Search Underpins Any Epidemiological Analysis Consisting of a Literature Review

In the field of epidemiology, "A reliable literature review 'uses formal search methods to allow a researcher to obtain a 'snapshot' of the existing research on a particular question.'" *In re Lipitor*, 174 F. Supp. 3d at 929 (quoting *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*,

No. 11cv5468, 2015 WL 5050214, at *3 (N.D. Ill. Aug. 25, 2015) (attached hereto as **Ex. 5**)). The epidemiologist's literature review "begins with a *formal, transparent, and reproducible search* for studies that address a proposed research question." *Id.* (emphasis added).

Dr. Flack himself agreed that a rigorous literature search is critical to a proper epidemiological analysis – with the focus on review of "the relevant studies." Dr. Flack testified as follows:

(Flack Dep. 121:6-122:22 (emphasis added).)

And indeed, when Dr. Flack himself publishes an epidemiological study *outside* of the litigation setting, he follows these tenets he set forth above. For example, in one of Dr. Flack's peer-reviewed published articles, he conducted a meta-analysis of trials using impedance cardiography ("ICG") in the treatment of hypertension. The literature search was described by Dr. Flack in the article as follows:

> Initially, we conducted a literature and reference search in Medline, PubMed, and Cochrane databases as well as the Internet for studies using ICG in the treatment of adults with hypertension. Key words searched were 'hypertension', 'resistant hypertension', 'hemodynamics', 'impedance cardiography', 'therapy individualization' and 'goal-directed therapy'. For inclusion in this review and meta-analysis, studies had to meet two of the following criteria: (1) randomization of adults with a history of mild to resistant essential hypertension and presence of a control group of patients randomly assigned to standard medical care for treatment of their hypertension; (2) nonrandomized, prospective, interventional clinical trial of adults demonstrating the impact of ICG-guided therapy on BP control and clinical outcomes; and/or (3) inclusion of detailed reporting of baseline BPs and BPs obtained after a predetermined treatment period using ICG-guided therapy. No studies meeting these criteria were excluded with the exception of women with toxemia in pregnancy. Table 1 summarizes the available studies meeting the inclusion criteria for analysis.

(Flack Dep. 117:3-18; Pl-Flack-9 (attached as **Ex. 3**).) This epidemiological "literature and reference search" was rigorous in the sense that it: (1) included numerous databases (Medline,

PubMed, Cochrane); (2) included numerous *disconnected* keywords guaranteed to be expansive enough to ensure capture of all potentially relevant studies; and (3) had pre-set inclusion criteria to ensure that Dr. Flack and his co-authors were not making *ad hoc* (or potentially biased) decisions about which studies to include or not include in the study. (Flack Dep. 119:4-120:21.)

2. Dr. Flack's "Literature Search" Was Informal, Non-Transparent, and Non-Reproducible, and Resulted in Cherry-Picked Evidence

Compare the above to what Dr. Flack did in this case for Section VIII of his Report. Although not reflected in his Report, Dr. Flack's testimony was that he searched one database (PubMed) and included only two *connected* search terms of "valsartan" **and** "NDMA" (i.e., both had to appear in the article to be captured by the search). (Flack Dep. 15:10-16:3 (testifying that [redacted]).) Running a search in this fashion (i.e., requiring the article to include the term "valsartan") virtually guaranteed that virtually all of the many *decades* of pre-recall research on NDMA, NDEA, and nitrosamines and their propensity to cause cancer (animal studies, dietary studies, occupational studies, *in vitro* mechanistic studies) would *not* be captured; all of that research occurred outside the context of the valsartan recall. And indeed, the result was that Dr. Flack only had two search hits on this search, both studies post-recall examining the effect of NDMA/NDEA contamination of valsartan, with significant author-acknowledged limitations that Dr. Flack conveniently ignored.

As for the remainder of the literature that appeared on Dr. Flack's list of "materials considered" appended to his Report as Exhibit B, he could not say where they came from. (Flack Dep. 14:5-12 & 128:18-129:4.) Dr. Flack could not even identify which of the materials provided to him (most of which was provided by counsel) he actually read. (Flack Dep. 58:6-9 [redacted]

[redacted].) Dr. Flack accordingly could not state that what defense counsel provided to him was not cherry-picked or one-sided, or even that he reviewed it.

This is the exact scenario Dr. Flack described as proving lack of reliability: [redacted] (Flack Dep. 121:11-122:6); *see also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 242 (S.D.N.Y. 2018) ("'[A]n expert may not 'pick and choose' from the scientific landscape and present the Court with what he believes the final picture looks like.' Where an expert ignores evidence that is highly relevant to his [or her] conclusion, contrary to his [or her] own stated methodology, exclusion of the expert's testimony is warranted.").

3. Dr. Flack Failed to Address the Dietary Studies Among Other Omitted Key Evidence from His "Analysis"

The effect of this unreasonably narrow literature search is not speculative or hypothetical in this case. Dr. Flack missed and failed to consider major *categories* of studies bearing directly on the question of NDMA/NDEA and cancer causation.

For example, Dr. Flack discusses nowhere in Section VIII of his Report the numerous dietary studies, all of which bear directly on NDMA/NDEA and human cancer causation. Dr. Flack's omission is particularly telling because they are exactly the types of studies Dr. Flack expressed a desire to see in his Report (Dr. Flack discounts animal studies in his Report based on dose exposures, and discounts the occupational studies based on method of administration (inhalation v. oral ingestion)). Nor does Dr. Flack grapple with the mechanistic studies, including several conducted on human tissue. In sum, this is not a case of an expert failing to account for a single study or two; these are *entire categories* of extremely relevant studies consisting of decades' worth of research omitted entirely from the analysis.

Notably, Dr. Flack cannot *post hoc* claim that he viewed these categories of studies and discounted them because he himself testified that it is important to address such studies up front even if to cast them aside:

(Flack Dep. 122:9-22.)

Even for the categories of studies Dr. Flack did address in Section VIII of his Report, there is no way he can verify that those studies have not been cherry-picked by counsel for the defendants since he did not do independent research other than the one inadequate search for valsartan and NDMA discussed above.

4. Dr. Flack Did Not Conduct a Weight of the Evidence/Bradford Hill Analysis

Even though he is asserting epidemiological opinions, Dr. Flack failed to conduct an adequate methodological analysis of the results of his so-called "literature review." For epidemiological opinions, federal courts including the Third Circuit require a weight of the evidence and/or Bradford Hill analysis, which has been deemed "generally reliable." *In re Zoloft*, 858 F.3d at 795. Not only must the expert conduct such an analysis, but "the specific techniques by which the weight of the evidence/Bradford Hill methodology is conducted must themselves be reliable according to the principles articulated in *Daubert*." *Id.* at 796.

Dr. Flack unquestionably did not conduct a Bradford Hill analysis. Those words appear nowhere in his Report, nor is there any discussion of the Bradford Hill criteria. To the extent Dr. Flack argues he conducted a "weight of the evidence" analysis, the exclusion of entire categories of scientific data – specifically, the dietary studies and mechanistic studies – is fatal to his approach.

5. The Court Should Exclude Dr. Flack's Opinions in Section VIII

The result should be the exclusion of Dr. Flack's unreliable opinions. In *In re Lipitor*, the court addressed a similar "literature review" expert opinion based on a flawed literature search and excluded the proposed expert's testimony:

> A reliable literature review 'uses formal search methods to allow a researcher to obtain a neutral 'snapshot' of the existing research on a particular question.' … [S]uch a review 'begins with a formal, transparent, and reproducible search for studies that address a proposed research question.'

In re Lipitor, 174 F. Supp. 3d at 929 (citing and quoting *In re Zimmer Nexgen Knee Implant Litig.*, 2015 WL 5050214, at *3).

The court then focused on a comparison of the plaintiffs' proposed expert's methodology when conducting a literature review for publication versus what he had prepared for his expert report. *Id.* at 930 ("The difference in Dr. Quon's methodology when conducting a literature review for publication and when preparing his testimony in this case is quite telling."). The Court focused on the ultimate goal, which is for the expert to be aware of and account for the relevant categories of evidence, whether pro or con. The Court found that the expert's "cherry-picking of data is unreliable and 'fails to satisfy the scientific method and *Daubert*'" and that the expert's "failing to adequately account for contrary evidence is not reliable or scientifically sound." *Id.* at 931-32. The court excluded the proposed expert's testimony. *Id.* at 933.

Dr. Flack's approach presents very similar methodological shortcomings and compels the same result. Dr. Flack's inadequate literature search resulted in the omission of ***decades*** of important literature (which ultimately resulted in the omission of entire categories of studies from his analysis); Dr. Flack admitted to having a different standard for publication-oriented literature searches than what he did in this case; and, Dr. Flack admitted that what he did in this case would be "blasted" if it was submitted for publication. *In re Mirena*, 341 F. Supp. 3d at 242; *In re Lipitor*, 174 F. Supp. 3d at 929-932; *Daniels-Feasel,* 2021 WL 4037820, at *5. Finally, Dr. Flack failed to conduct an appropriate epidemiological analysis that would meet *Daubert*'s standard in the context of an epidemiological study.

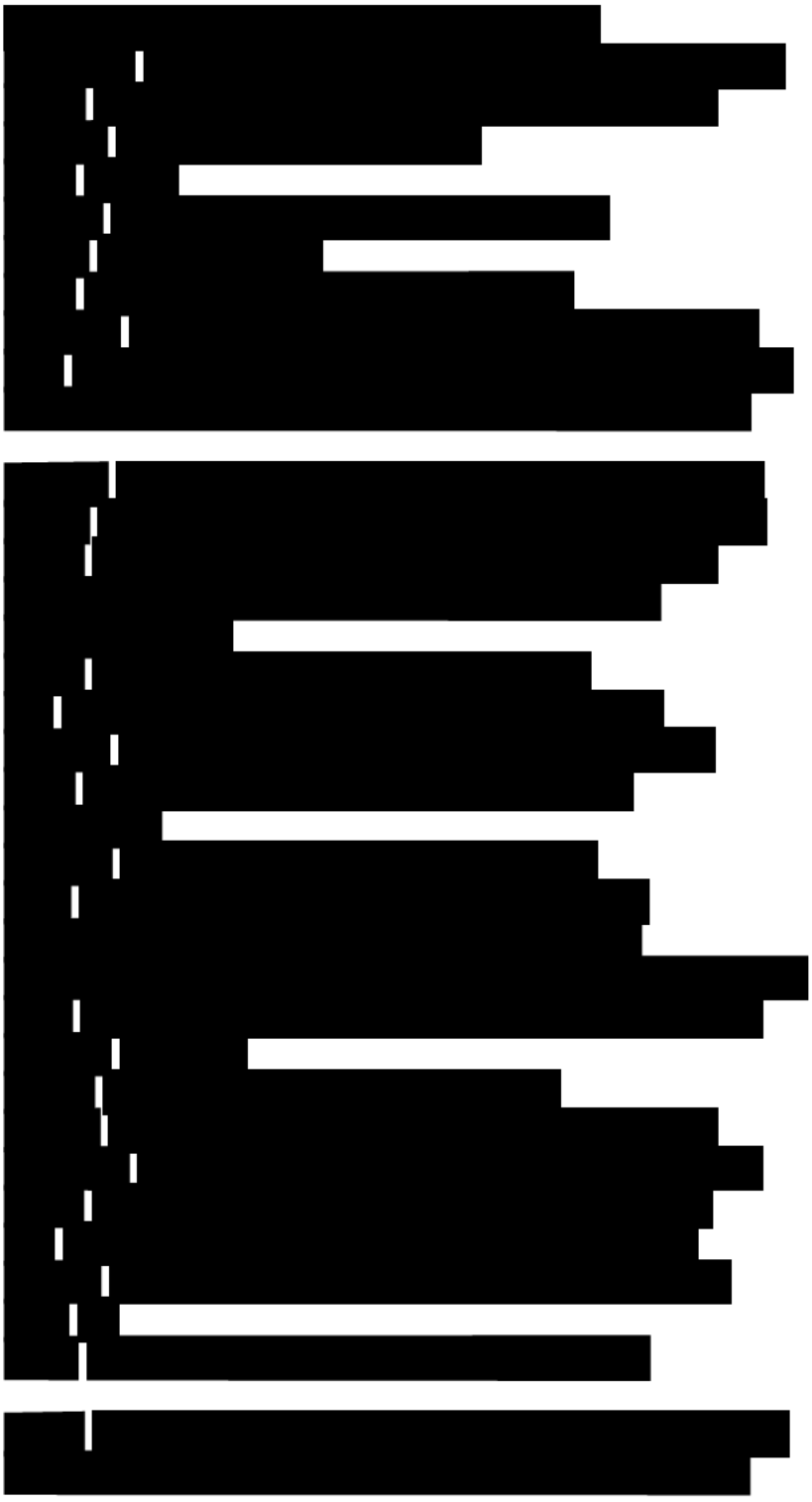
The law is clear that courts should hold experts to the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Elcock*, 233 F.3d at 746. There is no question that Dr. Flack failed to meet this standard in Section VIII of his Report.

D. Dr. Flack's *Retracted* Opinion in Section VII of his Report that He Did Not "Witness Any Patients Have an Adverse Effect" Lacks Any Supportable Basis or Methodology and Should be Excluded

Section VII of Dr. Flack's Report discusses the recall of the at-issue VCDs and the impact on patients, from Dr. Flack's perspective as a treating physician of hypertension patients. The last sentence of that section includes the following statement: "I did not witness any patients have an adverse effect as a result of the NDMA/NDEA impurities found in valsartan." (Flack Rep., at 30.)

To the extent that Dr. Flack's Report suggested this was an opinion regarding a lack of cancer diagnoses among his patients who were exposed to NDMA/NDEA-contaminated VCDs (which would be inadmissible on its face for multiple reasons), Dr. Flack clarified that this was not the import of the opinion at his deposition. Specifically, Dr. Flack clarified that he

only meant that he did not witness any adverse effects as a result of the recall itself, which required him to prescribe alternative therapies for his patients who had been prescribed the contaminated valsartan. Specifically, the following exchange occurred at Dr. Flack's deposition:



[redacted]

(Flack Dep. 177:14-179:3 (emphasis added).)

Plaintiffs do not seek to exclude Dr. Flack's observation that he did not witness any patients have difficulty finding appropriate alternative hypertension therapies. However, the Court should exclude Dr. Flack from offering any observations about cancer diagnoses among his patients exposed to NDMA/NDEA because Dr. Flack expressly disavowed under oath offering such an opinion. Disavowed opinions are clearly subject to exclusion. *See, e.g., Monje v. Spin Master inc.*, 679 F. App'x 535, 538 (9th Cir. 2017) ("The other theory was excluded as unreliable after the expert witness unambiguously disavowed the theory at his deposition … It was well within the district court's broad discretion to exclude both theories." (citations omitted)).

Dr. Flack admitted that he did absolutely nothing to rule out NDMA/NDEA exposure as contributing to any of his patients' cancer diagnoses:[3]

[redacted]

(Flack Dep. 181:22-182:8.)

[3] Such an opinion would lack any foundation as no information or records has been provided about the unidentified patients, and the opinion is devoid of any methodology.

The Court should exclude the opinions offered in Section VII of Dr. Flack's Report because Dr. Flack lacks qualifications to opine about cancer diagnoses that he never investigated, and then retracted the opinion under oath at his deposition.

E. Section IX of Dr. Flack's Report Depends on the Flawed Unreliable Analysis Found at Section VIII of His Report

Section IX of Dr. Flack's Report posits that it is "more likely" that shared risk factors between hypertension and cancer caused cancer than NDMA/NDEA contamination. (Flack Rep., at 39.) Section IX of Dr. Flack's Report cites no additional references, and Dr. Flack confirmed at his deposition that the Section is a synthesis section between Section III.O of his Report and Section VIII of his Report. (Flack Dep. 183:21-187:5.)

To begin with, it is far beyond Dr. Flack's expertise to opine regarding cancer diagnoses in the Plaintiffs and what caused them, and there is certainly no foundation for such a speculative opinion.

To the extent there is any new standalone opinion in Section IX it is limited to the comparative judgment that it is "more likely" that any individual plaintiffs' cancers are attributable to shared risk factors with hypertension and cancer than to NDMA/NDEA exposure. This is not a general causation opinion, however. "General causation is whether a substance ***is capable of causing*** a particular injury or condition[.]" *In re Johnson & Johnson Talcum Powder Prods. Mkt'ing Sales Practices and Prods. Litig.*, 509 F. Supp. 3d 116, 157 (D.N.J. 2020) (emphasis added). Attempting to pass judgment on what is "more likely" to have caused individual cancers is a specific causation opinion inappropriate for Dr. Flack to assert in this context, particularly when he testified he had not reviewed any individual plaintiff's records – rendering it a net opinion at best. (Flack Dep. 129:5-21.) To the extent Dr. Flack and Defendants contend Section IX of Dr. Flack's report is in fact a general causation opinion, that opinion –

which contains zero reference cites, Flack Dep. 186:22-187:5 – amounts to nothing more than unsupported and non-methodological speculation. In other words, Section IX of Dr. Flack's Report is saddled with the same issues as the other parts of the report relied on. The Court should exclude Dr. Flack's opinion in Section IX of his Report that plaintiffs' cancers are "more likely" to have been caused by shared risk factors between hypertension and cancer than by NDMA/NDEA exposure.

IV. CONCLUSION

For the foregoing reasons, Dr. Flack should be excluded from offering his opinions related to general causation, including those expressed in Sections III.O, VII, VIII and IX of his Report.

Dated: Nov. 1, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 1, 2021, I electronically filed a redacted version the foregoing document with the Clerk of the Court using the CM/ECF system which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL. In addition, I hereby certify that unredacted copies of foregoing document will be served contemporaneous to filing via email on the Court, Special Master, and the Defense Executive Committee at DECValsartan@btlaw.com.

/s/ John R. Davis
John R. Davis